

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 8, 2015

Findings Date: July 8, 2015

Project Analyst: Jane Rhoe-Jones

Assistant Chief: Martha J. Frisone

Project ID #: F-11023-15

Facility: Dialysis Care of Rowan County

FID #: 960504

County: Rowan

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than four dialysis stations for a total of no more than 27 stations upon completion of this project, Project ID# F-10273-14 (relocate one station to Dialysis Care of Kannapolis) and Project ID# F-10371-15 (relocate five stations to Dialysis Care of Kannapolis)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County proposes to add four dialysis stations for a total of 27 certified dialysis stations upon completion of this project, Project ID# F-10273-14 (relocate one station to Dialysis Care of Kannapolis) and Project ID# F-10371-15 (relocate five stations to Dialysis Care of Kannapolis). Prior to this application being submitted, the certificate of need was issued for Project ID# F-10273-14 on July 8, 2014, and a conditional approval was granted for Project ID# F-10371-15 on April 7, 2015. That CON was issued on May 8, 2015.

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of three dialysis stations in Rowan County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Dialysis Care of Rowan County in the January 2015 SDR is 3.3448 patients per station, or 83.6% (3.3448 / 4 patients per station = 0.8362). This utilization rate was calculated based on 97 in-center dialysis patients and 29 certified dialysis stations (97 patients / 29 stations = 3.3448 patients per station).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

DIALYSIS CARE OF ROWAN COUNTY - APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/14		83.62%
Certified Stations		29
Pending Stations		0
Total Existing and Pending Stations*		29
In-Center Patients as of 6/30/14 (SDR2)		97
In-Center Patients as of 12/31/13 (SDR1)		88
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.2045
(ii)	Divide the result of step (i) by 12	0.0170
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.1023
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	106.9205
(v)	Divide the result of step (iv) by 3.2 patients per station	33.4126
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	4

*Pursuant to the certificate of need for Project ID# F-10273-14, one station will be relocated to Dialysis Care of Kannapolis and pursuant to the certificate of Need for Project F-10371-15, five stations will be relocated to Dialysis Care of Kannapolis leaving 23 stations at Dialysis Care of Rowan County.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established . . . , up to a maximum of ten stations.*” The applicant proposes to add four new stations, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: BASIC PRINCIPLES, on page 38 of the 2015 State Medical Facilities Plan (SMFP) is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote quality in Section II.3, pages 19-20, and referenced exhibits. The applicant describes how it believes the proposed project would promote safety in Section XI.6(g), pages 66-67, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section VI, pages 35-40. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize healthcare value in Section III.9, pages 26-27. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need it has identified. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2015 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County proposes to add four dialysis stations, for a total of 27 certified dialysis stations upon completion of this project, Project ID# F-10273-14 (relocate one station to Dialysis Care of Kannapolis) and Project ID# F-10371-15 (relocate five stations to Dialysis Care of Kannapolis). Prior to this application being submitted, the certificate of need was issued for Project ID# F-10273-14 on July 8, 2014, and a conditional approval was granted for Project ID# F-10371-15 on April 7, 2015. That CON was issued on May 8, 2015.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where they are located. Thus, in this application, the service area is Rowan County. Dialysis facilities may serve residents of counties not included in their service area.

In Section IV.1, page 28, the applicant identifies the population served as of June 30, 2014, which is illustrated below in the table:

DIALYSIS CARE OF ROWAN COUNTY		
County of Residence	# of In-Center Patients	# of Home Dialysis Patients
Rowan	96	33
Davidson	1	0
Davie	0	2
Iredell	0	1
Stanley	0	1
TOTAL	97	37

In Section III.7, pages 24-26, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated below in the table:

DIALYSIS CARE OF ROWAN COUNTY: Projected Patient Origin						
County	Operating Year 1 2016		Operating Year 2 2017		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In Center Patients	Home Dialysis Patients	Year 1	Year 2
Rowan	107	37	113	38	96.6%	96.9%
Davidson	1	0	1	0	0.7%	0.6%
Davie	0	2	0	2	1.3%	1.3%
Iredell	0	1	0	1	0.7%	0.6%
Stanley	0	1	0	1	0.7%	0.6%
TOTAL	108	41	114	42	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In-center Patients

In Section III.7, pages 24-26, the applicant provides the assumptions and methodology used to project utilization, which are as follows:

- *“DC of Rowan County had 97 in-center patients and 29 certified stations as of June 30, 2014 based on the data reported in Table A of the January 2015 Semiannual Dialysis Report (SDR). See **Exhibit 7**. [Emphasis in original.]*
- *The January 2015 SDR indicates that the five year average annual change rate for Rowan County was 4.8%. It is reasonable to assume a 4.8% growth rate for DC of Rowan County patients living in Rowan County, ...*
- *Total Renal Care of North Carolina submitted a Certificate of Need application on March 17, 2014 to transfer one dialysis station from DC of Rowan County to DC of Kannapolis. That CON application was an in-county transfer of a station. No patients were projected to transfer to DC of Kannapolis. That CON application was approved and the station transfer will take place on January 1, 2016.*
- *Total Renal Care of North Carolina submitted a Certificate of Need application on January 15, 2015 to transfer five dialysis stations from DC of Rowan County to DC of Kannapolis. That CON application was an in-county transfer of a station [sic]. No patients were projected to transfer to DC of Kannapolis. That CON application is under review and, when approved, the station transfer will take place on January 1,*

2016. (That certificate of need application was conditionally approved on April 7, 2015 and the CON was issued on May 8, 2015.)

- *As a result of the transfer of dialysis stations to DC of Kannapolis, DC of Rowan County will have 27 dialysis stations as of January 1, 2016.*
- *Dialysis Care of Rowan County (DC of Rowan County) had 97 in-center patients as of June 30, 2014 based on information included in Table A of the January 2015 Semiannual Dialysis Report (SDR). This is a station utilization rate of 83.62% based on the 29 certified stations.*
- ...
- ...
- *It is projected that the one-station transfer and CON application that is under review for the five-stations [sic] transfer of stations to DC of Kannapolis will take place on January 1, 2016, the same day this four-station expansion is expected to be certified. DC of Rowan County would have a decrease of six dialysis stations, leaving the facility with 23 stations. The four-station expansion would increase the number of stations to 27.*
- *As of June 30, 2014, 96 of the in-center patients lived in Rowan County and one patient lived in Davidson County. Based on the calculations below, DC of Rowan County is projected to have at least 108 in-center patients by the end of operating year 1 for a utilization rate of 100% or 4.0 patients per station and at least 114 in-center patients by the end of operating year 2 for a utilization rate of 105% or 4.2 patients per station. ... However, prior to the facility reaching 100% capacity, Total Renal Care of North Caroling [sic] will submit a CON application to expand the station capacity utilizing the Facility Need Methodology.*
- *The period of the growth begins June 30, 2014 forward to December 31, 2017. ...*
- *June 30, 2014-December 31, 2014 – 96 patients X 1.024 = 98.304*
- *January 1, 2015-December 31, 2015 – 98.304 patients X 1.048 = 103.022592*
- *January 1, 2016-December 31, 2016 – 103.022592 patients X 1.048 = 107.09676743*
- *January 1, 2017-December 31, 2017 – 107.09676743 patients X 1.048 = 113.1501226*
- *No growth was calculated for the patient living in Davidson County.”*

By the end of Year One, the applicant projects to serve 108 in-center patients (107 from Rowan County and one in-center patient living outside of Rowan County) dialyzing on 27 stations for a utilization rate of 100% or 4.0 patients per station [$108 / 27 = 4.0 / 4.0 = 1.00$ or 100%]. The applicant projects 114 in-center patients (113 from Rowan County and one in-center patient living outside of Rowan County) at the end of Year Two for a utilization rate of 105% or 4.2 patients per station [$114 / 27 = 4.22 / 4.0 = 1.055$ or 105%]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

On page 25, the applicant states:

“... Prior to the facility reaching 100% capacity, Total Renal Care of North Carolina will submit a CON application to expand the station capacity utilizing the Facility Need Methodology.”

Home-Trained Patients

The applicant states:

- *“As of June 30, 2014, 33 of the 37 home-trained patients lived in Rowan County, two home-trained lived in Davie County and one home-trained patient lived in Iredell and Stanley Counties [one patient per Iredell and Stanley counties].*
- *Based on the calculations below, DC of Rowan County is projected to have at least 40 home-trained patients by the end of operating year [sic] and least 41 home-trained patients by the end of operating year 2. ...*

June 30, 2014-December 31, 2014 – 33 patients X 1.024 = 33.792

January 1, 2015-December 31, 2015 – 33.792 patients X 1.048 = 35.414016

January 1, 2016-December 31, 2016 – 35.414016 patients X 1.048 = 37.11388876

January 1, 2017-December 31, 2017 – 37.11388876 patients X 1.048 = 38.89535542

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access to Services

In Section VI.1, page 35, the applicant states:

“DC of Rowan County, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, sex, age, or handicap. We serve patients regardless of ethnic or socioeconomic situation.

...

DC of Rowan County does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

On page 35, the applicant projects no change as a result of this project in the percentage of its in-center patients that have all or part of their services covered by Medicare and/or Medicaid (73.47%). The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section III.9, page 26, the applicant discusses the alternatives considered for Dialysis Care of Rowan County, which are:

1. Maintain the Status Quo - the applicant dismissed this alternative based on the continued growth at the facility which means doing nothing would not be in the best interest of the patients of Dialysis Care of Rowan County.
2. Add four stations - the applicant concluded that the proposal to add four additional dialysis stations is its most effective alternative to meet the growing need for dialysis services at the Salisbury dialysis facility. Thus, the applicant concludes that the project as proposed is its least costly and most effective alternative.

The applicant adequately demonstrates the need for four additional stations based on the facility's projected utilization. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The application is conforming or conditionally conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County shall materially comply with all representations made in the certificate of need application.**
 - 2. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County shall develop no more than four additional stations for a total of no more than 27 stations upon completion of this project, Project ID# F-10273-14 (relocate one station to Dialysis Care of Kannapolis) and Project ID# F-10371-15 (relocate five stations to Dialysis Care of Kannapolis), which shall include any home hemodialysis training or isolation stations.**
 - 3. Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County shall submit documentation of an invitation to a professional training program in Rowan or a contiguous county to use the facility for training students.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII, page 45, the applicant projects that there will be no capital costs associated with the proposed project. In Section IX, page 50, the applicant projects no initial start-up costs or initial operating expenses because Dialysis Care of Rowan County is an existing facility.

In Section X.1, page 52, the applicant provides the allowable charges per treatment for each payment source for Dialysis Care of Rowan County, as illustrated below in the table:

Dialysis Care of Rowan County	
Payor	
Medicare	\$239.43
Medicaid	\$143.00
Medicare/Medicaid	\$239.43
Commercial Insurance	\$1,275.00
Medicare/Commercial	\$239.43
VA	\$193.00

On page 52, the applicant states that the reimbursement rates are the same for both in-center and home-trained patients and includes further details about charges and reimbursement rates.

In Section X.2-X.4, pages 53-60, the applicant projects revenues and operating expenses for Dialysis Care of Rowan County, as illustrated below in the table:

Dialysis Care of Rowan County		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$8,810,724	\$9,201,582
Total Operating Costs	\$5,971,774	\$6,215,064
Net Profit	\$2,838,950	\$2,986,518

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable and adequately supported. See Section X, pages 54-60, for the applicant's assumptions. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges to provide the proposed health services. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where they are located. Thus, in this application, the service area is Rowan County. Dialysis facilities may serve residents of counties not included in their service area.

The applicant proposes to add four dialysis stations to its existing facility for a total of 27 certified dialysis stations upon completion of this project, Project ID# F-10273-14 (relocate one station to Dialysis Care of Kannapolis) and Project ID# F-10371-15 (relocate five stations to Dialysis Care of Kannapolis). Although the January 2015 SDR shows there is a

surplus of three dialysis stations in Rowan County, in this application, the applicant is applying for additional stations based on the facility need methodology.

The applicant adequately demonstrates the need for four additional stations based on the number of in-center patients it currently serves and proposes to serve. The growth projections are based on Rowan County's projected five-year average annual growth rate in the number of dialysis patients, as published in the January 2015 SDR.

According to Table A in the January 2015 SDR, as of June 30, 2014, Dialysis Care of Rowan County was operating at 83.6% of capacity, with 97 in-center patients on 29 stations ($97 / 29 = 3.3448$; $3.448 / 4 = 0.8362$). The target utilization rate is 80% or 3.2 patients per station, per week, at the end of the first operating year. The utilization rate projected for Dialysis Care of Rowan County at the end of the first operating year is 4.0 patients per station, or 100% ($4 / 4$ patients per station = 1.00). This utilization rate was calculated based on 108 in-center dialysis patients and 27 certified dialysis stations ($108 \text{ patients} / 27 \text{ stations} = 4.0$ patients per station). This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by *10A NCAC 14C .2203(b)*. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

According to the January 2015 SDR, Dialysis Care of Rowan County in Salisbury is one of two existing dialysis facilities in Rowan County and both are owned by the same parent company, DaVita Healthcare Partners, Inc. The other facility, Dialysis Care of Kannapolis is located in Kannapolis. Dialysis Care of Kannapolis is certified for 25 stations and is currently serving 73 in-center patients, which is a utilization rate of 73% ($73 / 25 = 2.92$; $2.92 / 4 = 0.73$ or 73%). Travel between Salisbury and Kannapolis can take 26 minutes (17 miles) to 29 minutes (20.1 miles) depending on the route traveled. (*Google Maps*)

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis services in Rowan County. Consequently, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1, page 41, the applicant states that Dialysis Care of Rowan County currently employs 24.0 full-time equivalent (FTE) positions. The applicant does not propose to hire additional staff as a result of the proposed project. Note: at present the facility is certified for 29 stations; upon completion of all previously approved projects and this project, the facility would be certified for 27 stations. The applicant states on page 42, "*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405 .2100 [sic].*"

In Section VII.10, page 44, the applicant provides the current and projected number of direct care staff (patient care technicians) per shift offered:

DIALYSIS CARE OF ROWAN COUNTY							
	Shift Times	Mon	Tue	Wed	Thu	Fri	Sat
Morning	6am to 11am	8	8	8	8	8	8
Afternoon	11am to 4pm	8	8	8	8	8	8

In Section V.3, page 33, Section VII.2, page 42, and Exhibit 13, the applicant states that Dr. Ernest Johnson, M.D., currently serves as the Medical Director of Dialysis Care of Rowan County and has expressed his willingness to continue serving in that role.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.1, pages 30-31, the applicant lists the providers of the necessary ancillary and support services. Acute dialysis in an acute care setting, emergency care, diagnostic evaluation services, X-ray services, blood bank and vascular surgery are provided by Novant Health Rowan Medical Center. Exhibit 10 contains a copy of the Transplantation Agreement with Wake Forest University Baptist Medical Center (WFBUMC). The applicant adequately demonstrates the necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the

HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.1(b), page 36, the applicant reports that 73.5% of its in-center patients had some or all of their services paid for by Medicare and/or Medicaid, as illustrated in the following table.

DIALYSIS CARE OF ROWAN COUNTY IN-CENTER PATIENT UTILIZATION BY PAYOR SOURCE	
PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	20.41%
Medicaid	5.10%
Medicare/Medicaid	22.45%
Medicare/Commercial	25.51%
VA	9.18%
Commercial Insurance	17.35%
TOTAL	100.00%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Rowan, Davidson, Davie, Iredell and Stanley counties and statewide.

County	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Rowan	18.7%	7.6%	18.9%
Davidson	17.2%	6.9%	18.4%
Davie	13.5%	5.1%	17.3%
Iredell	14.0%	5.5%	18.3%
Stanley	17.4%	7.6%	18.3%
Statewide	16.5%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

Although, the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2013, over 84% of dialysis patients in North Carolina were 45 years of age and older. (ESRD Network 6 2013 Annual Report, page 101)¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the ESRD Network 6 2013 Annual Report provides prevalence data on North Carolina dialysis patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.²

The applicant demonstrates that the elderly and other medically underserved groups have adequate access to its existing services. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.1(f), page 38, the applicant states:

“DC of Rowan County has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. DC of Rowan County has no obligation under the Hill Burton Act.”

In Section VI.6(a), page 40, the applicant states: *“There have been no civil rights equal access complaints filed within the last five years.”* The application is conforming to this criterion.

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.1(a), page 35, the applicant states:

“DC of Rowan County, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, sex, age, or handicap. We serve patients regardless of ethnic or socioeconomic situation.

...

DC of Rowan County, does not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

In Section VI.1(c), page 36, the applicant projects no change in its current payor mix. Therefore, 73.5% of its in-center patients are expected to have some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table.

DIALYSIS CARE OF ROWAN COUNTY PROJECTED IN-CENTER PATIENT UTILIZATION BY PAYOR SOURCE	
PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	20.41%
Medicaid	5.10%
Medicare/Medicaid	22.45%
Medicare/Commercial	25.51%
VA	9.18%
Commercial Insurance	17.35%
TOTAL	100.00%

The applicant demonstrates that the elderly and other medically underserved groups would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.5, pages 39-40, the applicant describes the range of means by which patients will have access to the proposed services. The information the applicant provides in Section VI.5 is reasonable and credible and supports a finding of conformity to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

CA

In Section V(c), page 30, the applicant states “*DC of Rowan County has a Student Training Agreement with the Education Corporation of America. See Exhibit 12.*” [Emphasis in original.] The applicant provides a copy of the training agreement in Exhibit 12. However, the applicant does not adequately demonstrate that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conforming to this criterion subject to Condition 3 in Criterion (4).

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where they are located. Thus, in this application, the service area is Rowan County. Dialysis facilities may serve residents of counties not included in their service area.

DaVita HealthCare Partners, Inc., the parent company of Total Renal Care of North Carolina, LLC owns the two existing dialysis facilities in Rowan County; Dialysis Care of Rowan County in Salisbury and Dialysis Care of Kannapolis in Kannapolis.

Dialysis Care of Rowan County proposes to add four dialysis stations to its existing facility for a total of 27 certified dialysis stations upon completion of this project, Project ID# F-10273-14 (relocate one station to Dialysis Care of Kannapolis) and Project ID# F-10371-15 (relocate five stations to Dialysis Care of Kannapolis). Prior to this application being submitted, the certificate of need was issued for Project ID# F-10273-14 on July 8, 2014, and

a conditional approval was granted for Project ID# F-10371-15 on April 7, 2015. That CON was issued on May 8, 2015.

The applicant adequately demonstrates the need to add four dialysis stations to Dialysis Care of Rowan County and that it would not result in an unnecessary duplication. The discussions regarding need and duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

In Section V.6, pages 33-34, the applicant discusses how any enhanced competition in the service area will promote the cost effectiveness, quality and access to the proposed services. The applicant states:

“The proposed expansion of the facility is an effort to provide dialysis services to this community and is not intended to be a competitive venture. ...

... However, patient selection is the determining factor, as the patient will select the provider that ... best meets their needs. ...

... However, we do feel that accessibility to our services by the patients living in the service area identified will be enhanced.”

See also Sections I (pages 8-9), II (pages 14, 19-20), III (pages 26-27), V (pages 30-34), VI (pages 35-40), VII (pages 42-44) and referenced exhibits, where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13) are incorporated herein by reference.

The application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section I.13 and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.2202 INFORMATION REQUIRED OF APPLICANT

- (a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*

- (1) *Utilization rates;*

- C- In Section II.1, page 12, the applicant states the utilization rate is reported in the January 2015 SDR (provided in Exhibit 7). As of June 30, 2014, the utilization rate at Dialysis Care of Rowan County was 3.3 patients per station. This utilization rate was calculated based on 97 in-center dialysis patients and 29 certified dialysis stations (97 patients / 29 stations = 3.3448 patients per station).

- (2) *Mortality rates;*

- C- In Section IV.2, page 28, the applicant reports the 2012, 2013 and 2014 facility mortality rates were 20.2%, 14.1% and 14.5%, respectively.
 - (3) *The number of patients that are home trained and the number of patients on home dialysis;*
- C- In Section IV.3, page 29, the applicant states that as of December 31, 2014, Dialysis Care of Rowan County had 30 home-trained dialysis patients.
 - (4) *The number of transplants performed or referred;*
- C- In Section IV.4, page 29, the applicant states that in 2014, Dialysis Care of Rowan County referred 25 patients for transplant evaluation and three patients received a transplant.
 - (5) *The number of patients currently on the transplant waiting list;*
- C- In Section IV.5, page 29, the applicant states the facility has 18 patients on the transplant waiting list.
 - (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section IV.6, page 29, the applicant states that Dialysis Care of Rowan County had 194 hospital admissions in 2014; 34 (17.5%) of which were dialysis related and 160 (82.5%) of which were non-dialysis related.
 - (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section IV.7, page 29, the applicant states that there were no patients dialyzing at the facility with an infectious disease as of December 31, 2014. The applicant also states that there were no patients who converted to infectious status within the last year.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
 - (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*

- NA- Dialysis Care of Rowan County is an existing facility.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
 - (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- Dialysis Care of Rowan County is an existing facility.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- Dialysis Care of Rowan County is an existing facility.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 8, in which the applicant provides copies of written policies and procedures for back up electrical service in the event of a power outage.
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- Dialysis Care of Rowan County is an existing facility.
- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- In Section XI.6(g), page 66, the applicant states, “DC of Rowan County will continue to operate within the applicable laws and regulations pertaining to

staffing and fire safety equipment, physical environment, and other relevant health safety requirements.”

- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section III.7, pages 24-26, the applicant provides the projected patient origin, including all assumptions and the methodology by which the patient origin is projected, as illustrated below in the table.

DIALYSIS CARE OF ROWAN COUNTY: Projected Patient Origin						
County	Operating Year 1 2016		Operating Year 2 2017		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In Center Patients	Home Dialysis Patients	Year 1	Year 2
Rowan	107	37	113	38	96.6%	96.9%
Davidson	1	0	1	0	0.7%	0.6%
Davie	0	2	0	2	1.3%	1.3%
Iredell	0	1	0	1	0.7%	0.6%
Stanley	0	1	0	1	0.7%	0.6%
TOTAL	108	41	114	42	100.0%	100.0%

The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- Dialysis Care of Rowan County is an existing facility.

- (9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II.1(b)(9), page 14, the applicant states, “*Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County admits and provides dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

.2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per*

station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- Dialysis Care of Rowan County is an existing facility.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- By the end of Year One, the applicant projects to serve 108 in-center patients (107 from Rowan County and one in-center patient living in Davidson County) dialyzing on 27 stations for a utilization rate of 100% or 4.0 patients per station [$108 / 27 = 4.0 / 4.0 = 1.00$ or 100%]. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

.2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

(1) *diagnostic and evaluation services;*

-C- The table in Section V.1, page 30, states patients will be referred to Novant Health Rowan Medical Center for diagnostic and evaluation services.

(2) *maintenance dialysis;*

-C- The table in Section V.1, page 30, states the applicant will provide in-center maintenance dialysis at Dialysis Care of Rowan County.

(3) *accessible self-care training;*

-C- The table in Section V.1, page 30, states in-center hemodialysis, CAPD and CCPD will be provided by Dialysis Care of Rowan County.

(4) *accessible follow-up program for support of patients dialyzing at home;*

-C- The applicant addresses its accessible follow-up program for support of patients dialyzing at home in Section V.2(d), page 32.

(5) *x-ray services;*

- C- The table in Section V.1, page 30, states patients will be referred to Novant Health Rowan Medical Center for x-ray services.
- (6) *laboratory services;*
- C- The table in Section V.1, page 30, states patients will be referred to Dialysis Laboratories for routine and special laboratory services.
- (7) *blood bank services;*
- C- The table in Section V.1, page 30, states patients will be referred to Novant Health Rowan Medical Center for blood bank services.
- (8) *emergency care;*
- C- The table in Section V.1, page 30, states patients will be referred to Novant Health Rowan Medical Center for emergency care.
- (9) *acute dialysis in an acute care setting;*
- C- The table in Section V.1, page 30, states patients will be referred to Novant Health Rowan Medical Center for acute dialysis in an acute care setting.
- (10) *vascular surgery for dialysis treatment patients;*
- C- The table in Section V.1, page 31, states dialysis patients will be referred to Novant Health Rowan Medical Center for vascular surgery.
- (11) *transplantation services;*
- C- The table in Section V.1, page 30, states patients will be referred to Duke University Medical Center, Wake Forest University Baptist Medical Center and Carolinas Medical Center for transplantation services.
- (12) *vocational rehabilitation counseling and services; and*
- C- The table in Section V.1, page 30, states patients will be referred to Vocational Rehabilitation for vocational rehabilitation counseling and services.
- (13) *transportation.*
- C- The table in Section V.1, page 31, states patients will be referred to the Department of Social Services and various transportation providers.

.2205 STAFFING AND STAFF TRAINING

- (a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100 [sic].*
- C- In Section VII.1, page 41, the applicant provides the current and proposed staffing for Dialysis Care of Rowan County. On page 42, the applicant states, “*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 [sic] as evidenced below.*” Dialysis Care of Rowan County plans to continue having two dialysis shifts including direct care staffing of eight direct care personnel per shift on Monday through Saturday for both shifts. (See application, page 44.)
- (b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- In Section VII.5, page 43, the applicant refers the reader to Exhibit 17 for a copy of the training program description/outline. Exhibit 17 contains a copy of DaVita’s Training Programs for New Patient Care Provider Teammates. Exhibit 23 contains a copy of the Safety Training Outline and Exhibit 24 contains the Annual In-Service Calendar for Dialysis Care of Rowan County.